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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,220	07/02/2003	H. Garrett Wada	100/07211	7051

21569 7590 04/21/2004

CALIPER LIFE SCIENCES, INC.
605 FAIRCHILD DRIVE
MOUNTAIN VIEW, CA 94043-2234

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,220	WADA ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because it contain the application number of the parent case. Please submit a new oath/declaration identifying this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-12 and 16-23 rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al (USP#6,046,056).

Parce et al anticipates the instant invention by teaching microfluidic devices comprising first and second parallel microscale channels that are fluidly attached (See Figures 4A-4F). A first microscale channel has a separation region such that compounds that are immobilized on beads are separated by light or acid base prior to flowing the test compound down the reaction channel (column 17, lines 33-61). A second microscale channel contain a particle set such that individual beads settle into a

resting well after immobilized test compounds have been released (column 17, lines 33-50). A binding region is within parallel microscale channels such that a test compound will be contacted with a biochemical system for which an effector compound is being sought. The biochemical system may be a receptor-ligand mixture, a whole cell or beads that have enzyme/substrate systems immobilized thereon (column 17, lines 62-67 and column 18, lines 1-8). First and second detection regions can be within individual microscale channels such that a soluble signal is flowed out into the reaction channels along the detection channel past the detection window (column 19, lines 35-45). Fluid is controlled by fabricated fluid directions structures such as pumps and valves. More complex systems may be controlled by electroosmotic flow (column 18, lines 1-30). Fluid transport and direction is also accomplished through electrokinesis (column 13, lines 23-30). A microfluidic system may also contain devices that are connected to a computer for implementing operational instructions from the computer and for reporting data from the devices to the computer (column 22, lines 1-32). A detection system can be located adjacent to the detection window to monitor the signal levels (column 19, lines 46-47). A detector adjacent to the detection window monitors the level of fluorescent signal being produced by the enzyme activity on the fluorogenic or chromogenic substrate (column 14, lines 60-65). The test compound can be a variety of compounds such as polysaccharide, biological macromolecules, proteins, naturally occurring or synthetic. A number of solid supports can be made of glass, and polymeric material (column 7, lines 23-45). Separation channels may be treated and filled with high ionic strength buffer to allow separation of test components (column 16,

lines 41-55). Figures 4A-4E describe several channels fluidly connected in a parallel fashion, wherein particle-stacking regions are fixed within each channel. Claims 5-7 are concerned with the software programmed to direct the movement of fluid. Parce et al discloses that each device is connected to a computer system, which is appropriately programmed to control fluid flow and direction. The computer is programmed to analyze data resulting from the screening assays (column 22, lines 1-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al in view of Kurt G. I. Nilsson (USP#5,405,752).

The teaching of Parce et al are set forth above but is silent with respect to specific reagents.

The dependent claims recite avidin and biotin moieties that are not specifically described by the reference, however, the reference of Nilsson discloses the use of enzyme conjugates. Nilsson specifically discloses an avidin-biotin system which improves the sensitivity of an immunoassay. Nilsson discloses that avidin-biotin can be easily coupled to antibodies and other antigens without loss of activity and increased sensitive detection of spectral signals (column 13, lines 52-68).

Therefore, it would have been obvious to one of ordinary skill in the art to modifiy the reference of Parce et al who recites a variety of reagents that can be used as the test compound or binding moiety to include a avidin and biotin system because they are highly sensitive and well known in the art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

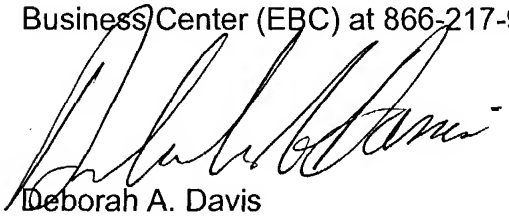
A. Manz et al teaches electroosmotic pumping in capillaries of small diameter used for chemical analysis (J. Micromech. Microengineering, 1994, Vol. 4, pages 257-265).

B. Seller et al teaches fluid flow driven network of intersecting capillaries integrated on a glass chip (Analytical Chemistry, 1994, Vol. 66, pages 3485-3491).

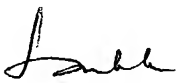
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah A. Davis
Remsen Bldg.
Room 3D58
April 13, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/09/04